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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

ANIMAL LEGAL DEFENSE FUND, *et al.*,

Plaintiffs,

v.

ALEX AZAR, *et al.*,

Defendants,

and

ELANCO ANIMAL HEALTH,

Intervenor-Defendant.

Case No. 3:20-cv-03703-RS

PLAINTIFFS' OPPOSITION TO DEFENDANTS' AND INTERVENOR'S MOTIONS TO DISMISS

Hearing Date: January 14, 2021
Hearing Time: 1:30 p.m.
Department: Courtroom 3

Honorable Richard Seeborg

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Federal Statutes

Federal Rules

Federal Regulations

INTRODUCTION

Plaintiffs Animal Legal Defense Fund (ALDF), Food & Water Watch (FWW), and Food Animal Concerns Trust (FACT) (collectively Plaintiffs) challenge a nationwide approval by the Food and Drug Administration (FDA or the Agency) that allows for the widespread agricultural use of Experior, a novel and controversial animal drug, in cattle feedlots across the country. The FDA approved Experior without adequately considering the animal health, public health, and environmental impacts of Experior's use. Within weeks of Experior's approval, Plaintiff ALDF petitioned the FDA to stay the approval unless and until the Agency conducted a more thorough analysis of these harms, one that complies with the FDA's statutory mandates under the Federal Food, Drug, and Cosmetic Act (FDCA) and the National Environmental Policy Act (NEPA). The FDA issued a final decision denying ALDF's petition, and in doing so, it acknowledged each of Plaintiffs' concerns and had the opportunity to address them.

Experior's imminent, widespread distribution harms Plaintiffs' members and threatens the natural environments and rural landscapes where they recreate and live. Plaintiffs' members are beef consumers who are harmed because they cannot avoid exposure to Experior in the food supply while consuming conventionally-raised beef and, because there is no way for them to know whether Experior is being used in the meat they purchase, they are forced to change their purchasing habits or forgo beef consumption altogether. Other members are rural residents who live and recreate in close proximity to beef feedlots where Experior is approved for use, and beef producers and business owners whose businesses stand to suffer from Experior's approval. All of these members rely heavily on the FDA to ensure animal drugs are safe, effective, and environmentally sound. Plaintiffs' injuries are legally cognizable under the FDCA and NEPA, directly traceable to the FDA's actions, and redressable by this Court.

Both the FDA's and Elanco's Motions to Dismiss overstate the standard of review at this early stage of litigation, mischaracterize the harms to Plaintiffs' members, and misconstrue Plaintiffs' allegations, claims, and requests for relief. Plaintiffs have amply established subject matter jurisdiction, have exhausted their administrative remedies, and have adequately pled their claims. The Court should deny the Motions.

BACKGROUND

Statutory Background. This action involves three statutes: the FDCA, NEPA, and the Administrative Procedure Act (APA). In enacting the FDCA in 1938, Congress provided the FDA with the authority and obligation to protect public health and safety by overseeing certain food products, drugs, and cosmetics. 21 U.S.C. § 393. The FDCA governs the use of all animal drugs. *Id*. § 360b. In order to legally sell an animal drug, the drug manufacturer must petition the FDA for approval in the form of a New Animal Drug Application, requesting the FDA to issue a regulation authorizing and prescribing lawful conditions for the drug's use. *Id*. § 360b(b)(1); 21 C.F.R. § 10.25(a)(1). The FDA's approval of an animal drug is a final agency action, published in the Federal Register, and effective immediately as a regulation under the FDCA. 21 U.S.C. § 360b(i).

In approving an animal drug, the FDA analyzes the drug's effects on human and animal health. *Id*. § 360b(d); 21 C.F.R. § 514.1. The FDA is also required to comply with NEPA and assess the effects of a drug on the environment *prior* to approving it. 21 C.F.R. §§ 514.1(b)(14), 25.1 ("All agencies of the Federal Government shall comply with the procedures in section 102(2) of NEPA except where compliance would be inconsistent with other statutory requirements."). The FDA is not required to engage in notice-and-comment rulemaking to issue new animal drug regulations, *id.* § 10.40(e)(3), and is exempt from public disclosure of drug-related information, *see id.* §§ 10.20(j), 20.61. Thus, the FDA typically does not make its approval and corresponding NEPA determination public until the Agency has taken final action.

The FDA regulations provide several ways that interested persons can challenge the FDA's administrative actions, including its approval of new animal drugs. The FDA regulations require that an interested person submit "a petition under § 10.25(a) . . . before any legal action is filed in a court complaining of the action or failure to act." *Id.* § 10.45(b). Section 10.25(a) creates a non-exhaustive list of potential petitions that an interested person may use to challenge an administrative action. One type of petition is a petition for a stay of action. *Id.* §§ 10.25(a)(1), 10.35(b). An interested person can, within 30 days of the approval, request that the FDA stay a

particular approval pending further review. *Id.* § 10.35(b). The FDA Commissioner must grant a stay in any proceeding if all of the following apply: (1) the petitioner will otherwise suffer irreparable injury; (2) the petitioner's case is not frivolous and is being pursued in good faith; (3) the petitioner has demonstrated sound public policy grounds supporting a stay; and (4) the delay resulting from the stay is not outweighed by public health or other public interests. *Id.* § 10.35(e)(1). The FDA's decision to grant or deny a petition to stay is a separate final agency action subject to immediate judicial review. *Id.* § 10.45(d).

NEPA is "our basic national charter for protection of the environment." 40 C.F.R. § 1500.1(a). The twin pillars of NEPA are the requirements that agencies (1) carefully evaluate the environmental impacts of major federal actions *before* undertaking the action, and (2) fully advise the public of the potential impacts of those actions. *Id.* § 1500.1.

In a NEPA analysis, the federal agency—here, the FDA—must identify the direct, indirect, and cumulative impacts of the proposed action and consider alternative actions and their impacts before making an irreversible and irretrievable commitment of resources. 42 U.S.C. § 4332(2)(C); 40 C.F.R. §§ 1508.7, 1508.8, 1502.14. "Impacts" include ecological, aesthetic, historic, cultural, economic, social, or health—a wide range of potential effects on the quality of the human environment. 40 C.F.R. § 1508.8. NEPA also requires agencies to evaluate economic or social and natural or physical environmental effects that are interrelated. *Id.* § 1508.14.

> NEPA procedures must insure that environmental information is available to public officials and citizens *before* decisions are made and before actions are taken. The information must be of high quality. Accurate scientific analysis, expert agency comments, and public scrutiny are essential to implementing NEPA.

Id. § 1500.1(b) (emphasis added).

The APA grants a right of judicial review to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . ." 5 U.S.C. § 702. Under the APA, a court must "hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . ." *Id.* § 706(2)(A). A court must also "hold unlawful and set aside" any agency action taken that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." *Id.* § 706(2)(C).

Finally, a court shall also "hold unlawful and set aside" any agency action that was promulgated "without observance of procedure required by law." *Id.* § 706(2)(D).

The section of the APA governing preliminary relief allows "the reviewing court" to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings" to "the extent necessary to prevent irreparable injury." *Id.* § 705. It therefore authorizes courts to stay agency action pending judicial review.

Factual Background. On November 6, 2018, the FDA approved Experior, a beta 3-adrenergic agonist/antagonist ("*β*3-AA") animal drug. First Amended Complaint (FAC) ¶ 1. Beta-adrenergic agonist/antagonist ("*β*-AA") drugs like Experior are linked to significantly higher mortality rates in cows due to a host of fatal respiratory, cardiac, and digestive issues, in addition to significant behavioral issues that make animals more likely to be abused and suffer in ways that directly impact food safety and worker health. *Id*. ¶ 3. These drugs also contaminate the human environment, *id.* ¶ 3, and can harm endangered wildlife and aquatic species, *id.* ¶ 156.

On December 6, 2018, Plaintiff ALDF submitted a Petition for Stay of Action (Stay Petition) to the FDA concerning the Experior approval. *Id.* ¶ 10. The Stay Petition articulated the particular reasons why the FDA's approval was improper. For example, the Stay Petition illustrated that Experior has not been shown to be safe and effective in target animals, in violation of the FDCA, because Experior may have significant adverse consequences for animal health, including heat stress, lameness, and sudden death, and because neither Elanco nor the FDA could make reliable predictions about the effectiveness of Experior at a herd, farm, or larger scale. *Id.* ¶ 126. The Stay Petition further illustrated the potential for Experior to cause significant harm to the environment, underscoring the FDA's duty to prepare an Environmental Impact Statement under NEPA. *Id.* The Petition explained that the FDA's NEPA documents failed to consider any alternatives to the approval or to even mention threatened and endangered species, also violating NEPA. *Id.* The Stay Petition showed that Experior is unsafe, or at best, that the FDA lacked sufficient information to approve the drug. *Id.* An approval that does not meet the FDCA's and NEPA's requirements causes irreparable harm to Plaintiffs because it

allows the use of a drug with known and unknown risks to target animal safety, human health, and the environment. *Id*. The Stay Petition requested that the FDA "stay" or halt the approval of Experior, not permanently, but until the time at which it corrected these and other deficiencies and brought the agency action into compliance with the referenced statutes. *Id.*

The FDA denied the Petition on May 20, 2019. FAC ¶ 128. In doing so, it acknowledged—although it failed to adequately address—the concerns Plaintiffs raised in the Stay Petition. FAC ¶ 130. The FDA's response did not contain sufficient data to refute or confirm the possible target animal safety impacts posed by Experior, could not confirm the effectiveness of Experior, and highlighted the myriad unknowns of how Experior will affect cows raised for beef when used under expected conditions. *Id.* On May 21, 2019, one day after denying ALDF's Petition, the FDA approved additional drugs that combine the original Experior formulation with controversial antibiotics tylosin and monensin. *Id.* ¶ 131. These combination drug approvals are tiered to the original Experior approval, so that the deficiencies therein continue to allow Experior-containing drugs to proliferate in the food supply. *Id.*

STANDARD OF REVIEW

In deciding a motion to dismiss, courts must accept "all factual allegations in the complaint as true" and construe them "in the light most favorable to the nonmoving party." *Skilstaf, Inc. v. CVS Caremark Corp.*, 669 F.3d 1005, 1014 (9th Cir. 2012). Courts must similarly draw all reasonable inferences from the complaint in favor of the nonmoving party and presume "general allegations embrace those specific facts that are necessary to support the claim." *Maya v. Centex Corp.*, 658 F.3d 1060, 1068 (9th Cir. 2011) (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 889 (1990)). Motions to dismiss for lack of jurisdiction and for failure to state a claim under Federal Rules of Civil Procedure (FRCP) 12(b)(1) and 12(b)(6), respectively, are both governed by the notice pleading requirements of FRCP 8(a), which states that a complaint need only contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2); *Dichter-Mad Family Partners, LLP v. U.S.*, 709 F.3d 749, 761 n.10 (9th Cir. 2013) (citations omitted). Specific facts are not required, so long as the factual allegations in the complaint, accepted as true, "state a claim to relief that is plausible on its face."

Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)); *see also Lacey v. Maricopa Cty.*, 693 F.3d 896, 911 (9th Cir. 2012). In reviewing a facial attack on subject matter jurisdiction pursuant to Rule 12(b)(1) or dismissal under Rule 12(b)(6), such as the motions here, courts construe a complaint liberally, accepting all allegations as true and drawing all reasonable inferences in plaintiffs' favor. *Compare Wolfe v. Strankman*, 392 F.3d 358, 362 (9th Cir. 2004) (holding that a facial attack argues that the complaint taken at face value is insufficient to invoke federal jurisdiction), *with Safe Air for Everyone v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004) (holding that a factual attack disputes the truth of the allegations in the complaint necessary to establish jurisdiction), *and Barker v. Riverside Cty. Office of Educ.*, 584 F.3d 821, 824 (9th Cir. 2009) (holding that, in reviewing an action pursuant to Rule 12(b)(6), the court must "accept as true the facts alleged in the complaint" and "draw inferences in the light most favorable to the plaintiff."). Plaintiffs may provide supplemental evidence on the pleadings to respond to a "facial" jurisdictional challenge 12(b)(1) motion. *See Warth v. Seldin*, 422 U.S. 490, 501–02 (1975).

ARGUMENT

I. Plaintiffs Have Standing.

Plaintiffs have adequately alleged Article III standing on behalf of themselves and their members.[1] To satisfy Article III's standing requirements, a plaintiff must show "(1) it has suffered an 'injury-in-fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc., v. Laidlaw Envtl. Servs. (TOC), Inc.,* 528 U.S. 167, 180–81 (2000) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)).

Plaintiffs' burden of establishing standing at the motion to dismiss stage is "relatively modest," *see Bennett v. Spear*, 520 U.S. 154, 171 (1997); "general factual allegations of injury

[1] All Plaintiffs allege associational standing based on injuries to their members and not organizational standing on their own behalves. *See Hunt v. Wash. State Apple Growers Ass'n*, 432 U.S. 333, 343 (1977) (explaining associational standing).

resulting from the defendant's conduct may suffice, for on a motion to dismiss [the Court] presume[s] that general allegations embrace those specific facts that are necessary to support the claim." *Defs. of Wildlife*, 504 U.S. at 561; *Maya*, 658 F.3d at 1068; *see also Abigail All. for Better Access to Developmental Drugs v. Eschenbach*, 469 F.3d 129, 132 (D.C. Cir. 2006) ("At each stage of trial, the party invoking the court's jurisdiction must establish the predicates for standing '*with the manner and degree of evidence required at that stage of trial*.'") (emphasis added) (quoting *Defs. of Wildlife*, 504 U.S. at 561). Thus, any later-stage challenges to the factual underpinnings of Plaintiffs' well-pled claims are not appropriate at the motion to dismiss stage. *Baur v. Veneman*, 352 F.3d 625, 641–42 (2d Cir. 2003).

Plaintiffs have presented sufficient evidence that their members are presently suffering injury-in-fact, and their harm is both traceable to the FDA's action and redressable by this Court. Plaintiffs thus have adequately pled standing at the motion to dismiss stage.

A. Plaintiffs Have Adequately Alleged Associational Standing.

To allege associational standing, an organization must show "that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit. . . ." *See Hunt*, 432 U.S. at 342. Thus "an association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Id.* at 343.

Because each Plaintiff organization, including FACT, has alleged representational standing based on harms to individual members,[2] and because no Plaintiff alleges organizational

[2] Valentine Decl. ¶ 1 (ALDF member); Kowalski Decl. ¶ 1 (ALDF member); Walden Decl. ¶ 4 (explaining ALDF membership); Bearce Decl. ¶ 1 (FACT member); Roach Decl. ¶ 4 (explaining FACT membership); Lobdell Decl. ¶ 2 (FWW member); Schutt Decl. ¶ 2 (FWW member); Merkel Decl. ¶ 4 (explaining FWW membership).

standing on its own behalf, FDA's arguments on this point are largely moot.[3] Indeed, if the Court finds that at least one member of one Plaintiff organization has alleged facts sufficient to support standing, the other standing arguments need not be addressed. *Leonard v. Clark*, 12 F.3d 885, 888 (9th Cir. 1993) ("The general rule applicable to federal court suits with multiple plaintiffs is that once the court determines that one of the plaintiffs has standing, it need not decide the standing of the others."); *Nat. Res. Def. Council v. FDA*, 710 F.3d 71, 80 (2d Cir. 2013) ("Since NRDC need only show that at least one of its members has standing to sue individually in order to establish representational standing, we focus exclusively on the declaration of [one member] because it is sufficient to satisfy this requirement . . . .").

B. Plaintiffs Have Adequately Alleged Injury-in-Fact.

Plaintiffs' injuries under both the FDCA and NEPA are sufficiently concrete and particularized and actual or imminent to satisfy Article III standing. While Experior's distribution in the food supply is imminent by Elanco's own admission, Plaintiffs are presently injured as a result of the FDA's approval even if Elanco is not yet being marketed. Their injuries are the type expressly recognized as conferring standing on plaintiffs under the FDCA and NEPA.

1. Experior's Presence in the Food Supply is Imminent.

The thrust of the Motions to Dismiss is that Plaintiffs have filed this suit too soon, because Experior is not yet in the food supply and there is no way for Plaintiffs to know which specific feedlots will use Experior. While the FDA and Elanco both misstate the harms alleged in Plaintiffs' Complaint and the case law governing injury-in-fact, as explained below, their arguments also attempt to permanently insulate themselves from judicial review: they know Plaintiffs will never be able to obtain the information necessary to assert with certainty where

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[3] Plaintiff FACT has submitted supporter declarations in addition to a member declaration. *See* Peters Decl. ¶ 1 (FACT supporter); Valentine Decl. ¶ 2 (same); Roach Decl. ¶ 6–7 (explaining FACT's supporters). The Court can consider harms to FACT's supporters because they function as members of a traditional membership organization would. *See Or. Advocacy Ctr. v. Mink*, 322 F.3d 1101, 1110–12 (9th Cir. 2003); *see also Gettman v. Drug Enf't Admin.*, 290 F.3d 430, 435 (D.C. Cir. 2002) (explaining how even non-membership organizations can satisfy the associational standing requirements under *Hunt* so long as "the organization is the functional equivalent of a traditional membership organization.") (internal quotations omitted).

Experior is being used, because *now that Experior is approved*, there is no regulatory mechanism that requires feedlots, Elanco, or the FDA to track Experior's use in the food supply. They therefore ask Plaintiffs to wait for a day that will never come, by misleadingly suggesting Plaintiffs can come back to the Court with evidence of Experior's use that will never exist—and that even the FDA and Elanco will never have.

While it is not surprising that the FDA has no idea when Experior will come to market given that it does not track such information, Elanco's claims of uncertainty about its own product are simply disingenuous. Elanco has been promising Experior's imminent entry into the market to its investors for at least the past four months. *See* Statement of Jeffrey Simmons, President and Chief Executive Officer, ELAN Q2 2020 Earnings Call (July 30, 2020), available at https://investor.elanco.com/events-and-presentations/default.aspx#module-event-upcoming ("[W]e've said publicly about having five launches on track during the rest of this year and into next year. That includes the Cosabody and Experior that we talked about."). Indeed, just eight days after filing its brief Elanco represented to its investors that the company planned on bringing Experior to market before the end of 2021. *See* Statement of Jeffrey Simmons, President and Chief Executive Officer, ELAN Q3 2020 Earnings Call (Nov. 6, 2020), available at https://investor.elanco.com/events-and-presentations/default.aspx#module-event-upcoming (stating that "Experior and Cosabody remain on track toward at least five launches by the end of 2021" and that "some additional . . . first-in-class, best-in-class products like Experior" are included in their 2021 projections). Elanco cannot have it both ways by representing one thing to its investors and another to the Court. Taking Elanco at its word, Experior's presence in the food supply is imminent.

Regardless, Plaintiffs meet the imminence requirements of injury under the specific standards of the FDCA and under NEPA, as explained below. Plaintiffs can and have adequately alleged injury-in-fact even without the information the FDA and Elanco find crucial to Plaintiffs' claims. To be persuaded otherwise would accomplish their goals of forever insulating FDA drug approvals from judicial review.

2. FDA's Approval of Experior Causes Plaintiffs to Suffer Legally-Cognizable Harms.

Plaintiffs' members and supporters are beef consumers, beef producers, outdoor enthusiasts, and rural residents who live and recreate adjacent to or in close vicinity of beef feedlots where Experior is approved for use.[4] Their injuries are precisely the kinds of concrete, particularized, actual, and imminent injuries that are legally cognizable under the FDCA and NEPA.

Plaintiffs' consumer members wish to avoid potentially unsafe animal drug residues—and Experior, specifically—in beef because of concerns for their own health and for the welfare of the cows to whom it is administered. *See, e.g.,* Peters Decl. ¶¶ 4, 9; Bearce Decl. ¶ 5. These members would like to consume conventionally-raised beef with confidence in its safety and with trust that the FDA has carried out its duties to keep such foods, and the animals who comprise them, safe. *E.g.,* Valentine Decl. ¶ 7; Peters Decl. ¶ 11. Because it is exceedingly difficult for consumers to obtain post-approval information about animal drug use, and because they cannot always find or afford premium, drug-free beef, they rely on the FDA to ensure the safety of animal drugs that may end up in the animal products they consume. *E.g.,* Peters Decl. ¶¶ 6, 12; Bearce Decl. ¶ 7. Because the FDA has failed to carry out its duties when approving Experior, their confidence in the safety of the beef supply has been eroded, and the FDA's burden has shifted to them to ensure the beef they are eating is actually safe. *E.g.,* Valentine Decl. ¶ 9; Peters Decl. ¶ 13; Kowalski Decl. ¶ 11.

The FDA's approval has allowed Experior to be used in the food supply immediately, but there is no way for consumers to know whether Experior is actually in a given beef product. As a

[4] *See, e.g.,* Merkel Decl. ¶ 4 (FWW's "membership base includes consumers, farmers, ranchers, and outdoor enthusiasts, who not only support our mission but are personally affected by the proliferation of the animal agriculture industry and its pervasive negative effects."); Walden Decl. ¶ 4 (ALDF's "membership base includes animal guardians, consumers, farmers, ranchers, and outdoor enthusiasts, who not only support our mission but are personally affected by the proliferation of CAFOs and the pervasive negative effects of CAFO industry practices, including on food safety."); Roach Decl. ¶ 4 (FACT "members consist of individuals with differing areas of expertise, but all with a commitment to advancing humane farming practices and improving safety within our food system. Some members have a professional interest in FACT's mission, as their work as farmers or business owners is impacted by the issues that FACT works on.").

result of the FDA's approval and the corresponding uncertainty about Experior's use, they are forced to alter their purchasing habits by spending more time, energy, and money sourcing drug-free beef products, *e.g.,* Kowalski Decl. ¶ 10; they forego beef consumption altogether when they cannot obtain meat that they trust to meet the FDCA's standards of safety, *e.g.,* Peters Decl. ¶ 6; and when they do eat conventionally-raised beef, they are forced to risk exposure to Experior residues and worry more about how it will affect their health, *e.g.,* Valentine Decl. ¶ 6, Peters Decl. ¶ 6, Bearce Decl. ¶ 7, Monaghan Decl. ¶ 9. Members who are pregnant, Monaghan Decl. ¶ 10, or who require medication that may interact with Experior, Valentine Decl. ¶ 8, are particularly at risk. All of these consumer members are at risk of exposure to Experior as a result of the FDA's approval, and also at risk of exposure to Experior when added to the cumulative amount of drug residues they already consume through cow, pig, and turkey products. *E.g.* Peters Decl. ¶ 10; Bearce Decl. ¶ 8; Kowalski Decl. ¶ 13; Monaghan Decl. ¶ 10. Moreover, members of Plaintiff organizations do not want to consume animals who have been given Experior because of the risks it poses to the animals and themselves. *E.g.,* Valentine Decl. ¶ 10; Peters Decl. ¶¶ 5, 8, 14; Bearce Decl. ¶ 9; Kowalski Decl. ¶ 10, Monaghan Decl. ¶ 11.

Members of Plaintiff organizations are further harmed by the risks Experior presents to the environment and by the FDA's inadequate consideration of such effects.[5] *See, e.g.,* Schutt Decl., Lobdell Decl., Bearce Decl., Kowalski Decl. Plaintiffs' members reside directly on the banks of Lake Michigan and the Upper Mississippi River, for example—areas of the country in which beef production is heavily concentrated, and which are significantly impacted by contaminants from cow manure on surrounding feedlots. *E.g.,* Bearce Decl. ¶¶ 11–15; Kowalski ¶¶ 2, 4–7. These members would recreate in and along their local waterways but for their desire to avoid direct contact with animal drug-laden feedlot pollution. *E.g.,* Bearce Decl. ¶¶ 11–16; *see also* Schutt Decl. ¶ 8. They also worry about the wild animals who make their homes there,

[5] While the Motions to Dismiss suggest that Plaintiffs' members will only suffer environmental harms if CAFO waste is mismanaged, the harms Plaintiffs allege result directly from decisions within the FDA's jurisdiction—the presence of Experior in animal manure—and from information the FDA was required to consider in its own analysis—the amount of Experior excreted by cows and how long it persists in the environment. *See, e.g.,* FAC ¶ 74 (Experior, with a half-life of 723 days, "persists in the environment long after it is excreted.").

whom they enjoy admiring in their natural habitats. *E.g.,* Bearce Decl. ¶¶ 11, 14; Kowalski Decl. ¶¶ 6–8. Another member's enjoyment of recreating in Lake Lewisville, Lake Ray Roberts, and Lake Grapevine in Texas is diminished by Experior's approval for use in surrounding feedlots. Monaghan Decl. ¶¶ 15–20. Still another member recreates and views wildlife extensively throughout Idaho, and predominantly in the Snake River in the Morley Nelson Snake River Birds of Prey National Conservation Area. Because this conservation area is immediately adjacent to and downstream of several conventional feedlots, including one of the largest in the world, this member's ability to recreate and enjoy wildlife in this area is severely threatened by the FDA's allowance of Experior in the food supply and corresponding failure to consider the effects of Experior in the environment. *E.g.,* Lobdell Decl. ¶¶ 6–8, 14. These members are injured by Experior's approval both because of Experior on its own and in combination with other drugs in the environment. *E.g.,* Lobdell Decl. ¶ 10; Bearce ¶ 13; Kowalski ¶ 13; Schutt Decl. ¶ 10.

One of FACT's members is a beef producer whose business is negatively impacted by the FDA's decision to allow this drug in the market without adequately assuring its safety. It is critically important to his business that beef consumers trust that what they are eating is safe, and the FDA's faulty decision erodes consumers' faith in their ability to source safe, drug-free meat, including from his business. Bearce Decl. ¶ 10. One ALDF member is further exposed to, and worried about her exposure to, Experior through her drinking water due to her private well's proximity to feedlots and impacted waterways. Kowalski Decl. ¶ 9. One of FWW's members lives next door to (within 1900 feet of) a conventional beef feedlot that land-applies manure from its 2500 cows; he has no way of protecting himself—including his drinking water source—from exposure to Experior through that feedlot now that Experior is allowed to be used there. Schutt Decl. ¶¶ 5–7. And all of Plaintiffs' consumer and environmental harms are compounded by the FDA's failure to ensure Experior is effective for its intended purpose. *See* Merkel Decl. ¶¶ 13–14; Walden ¶¶ 17–18; Roach Decl. ¶¶ 14–15, 19.

As explained below, each of these harms are paradigmatic injuries that confer standing on Plaintiffs under the FDCA and NEPA.

3. Plaintiffs' Harms Constitute Injury-in-Fact Under the FDCA.

Under the Federal Food, Drug, and Cosmetic Act, uncertain exposure to substances that the FDA has not found to be safe gives rise to injury-in-fact based not on future harm, but present risk. *Baur,* 352 F.3d at 640–41. Even where, like here, the allegedly harmful product could be but has not yet been found in the food supply, and thus a plaintiff cannot allege any direct exposure to it, a consumer plaintiff can show injury-in-fact based on the "exposure *to an enhanced risk*" that the product presents. *Id.* at 628; *Nat. Res. Def. Council*, 710 F.3d at 81.

In *Baur*, the plaintiff sought to compel the FDA to regulate beef products from nonambulatory cows (who are particularly likely to be infected with "mad cow" disease) arguing that allowing such products in the food supply violates the FDCA, among other things. 352 F.3d at 628. The lower court dismissed the suit for lack of standing, and the United States Court of Appeals for the Second Circuit reversed, holding that "exposure to an enhanced risk" of harm qualifies as present injury-in-fact in consumer food and drug safety suits, and that Baur had alleged a "credible risk of harm" at the motion to dismiss stage. *Id.* In doing so, the court expressly rejected the same argument the FDA and Elanco make here, i.e. that any harm is too speculative and remote, because mad cow disease had never been detected in the food supply. *Id.* at 630–31. The court held that "[i]n the specific context of food and drug safety suits," *present* injury based on *risk* of future injury is "cognizable for standing purposes, where the plaintiff alleges exposure to potentially harmful products." *Id*. at 634; *see also Nat. Res. Def. Council*, 710 F.3d at 81 (stating that under the FDCA, "the injury contemplated by exposure to a potentially harmful product is not the future harm that the exposure risks causing, but the *present exposure to risk*."). Thus, despite not being able to show any actual or even likely exposure in the future, Baur had standing at the motion to dismiss stage based on his credible threat of harm in the form of increased risk of exposure. 352 F.3d at 637–42. *Baur* explicitly recognized that at the pleading stage, a plaintiff could assert "more than a merely speculative" risk of harm from possible exposure even if he could not say with certainty that he would ever be exposed to it; any later challenges to the factual underpinnings of the claims are not appropriate at the motion to dismiss stage. *Id*. at 633.

While the dangers of mad cow disease in *Baur* were well known, "plaintiffs need not show that [an animal drug] is actually harmful in order to satisfy the requirements of standing" under the FDCA. *Stauber v. Shalala*, 895 F. Supp. 1178, 1187–88 (W.D. Wis. 1995); *Nat. Res. Def. Council*, 710 F.3d at 79–80 (holding that, though there was "scientific uncertainty as to whether triclosan is harmful to human health," plaintiffs presented enough evidence of its potential harmfulness to satisfy the injury-in-fact requirement). "Because the act places the responsibility on the sponsor of the drug to demonstrate the drug's safety and directs the FDA to approve for marketing only those drugs whose safety has been demonstrated, any significant uncertainty regarding the drug's safety is a burden to be borne by the sponsor, not the consumer." *Stauber*, 895 F. Supp. at 1187–88. Thus, where plaintiffs allege "FDA has failed to follow the dictates" of the FDCA in a manner that "has shifted the costs of uncertainty from the sponsor of the drug to the American consumer," including by leaving them unable to consume particular products with certainty that they are free of a potentially unsafe drug, they suffer cognizable injury-in-fact in the form of "increased risk of potential harm" due to FDA's action. *Id*. In holding that consumers have standing under the FDCA based on exposure to the potentially unsafe animal drug "rBST" in dairy products, the court in *Stauber* rejected the same argument the FDA and Elanco make here, and held that the burden of "increased risk of potential harm" constitutes an injury-in-fact for purposes of the consumers' standing. *Id.*; *see also Nat. Res. Def. Council*, 710 F.3d at 76–77.

Such is the case here. Plaintiffs' consumer members are entitled to a food supply free of potentially unsafe foods, and they rely on the FDA to accomplish that. Because the FDA has failed to ensure Experior is actually safe (and evidence suggests Experior is not actually safe), the FDA's burden has now shifted to consumers. Not only have they lost confidence in the safety of conventionally-raised beef products, but now that Experior has been approved, consumers have no meaningful way of avoiding Experior without altering their purchasing and consumption habits; incurring additional costs, time, and worry; or foregoing beef altogether. As a result of the FDA's approval and the corresponding uncertainty about Experior's use, consumers are forced to risk exposure to Experior residues and its corresponding health effects. *See, e.g.,* Peters Decl.

¶¶ 6, 12–13; Bearce Decl. ¶ 7; Valentine Decl. ¶ 9; Kowalski Decl. ¶ 11. This constitutes a credible risk of harm under the FDCA sufficient at the motion to dismiss stage.

Because of these well-pled injuries to Plaintiffs' members, the FDA's and Elanco's reliance on *Clapper v. Amnesty International USA*, 568 U.S. 398 (2013), to defeat Plaintiffs' claims is misplaced. *Clapper* does not preclude plaintiffs from establishing standing under the FDCA where they are presently suffering an increased risk of exposure to a potentially unsafe animal drug. *See Nat. Res. Def. Council,* 710 F.3d at 83 (rejecting *Clapper*'s application to FDCA claims because the "FDA's failure to regulate triclosan led to 'increased health-related uncertainty' arising from exposure to triclosan, a form of injury that this Court has recognized as sufficient to constitute an injury in fact.") (citations omitted). This Court has specifically rejected agencies' reliance on *Clapper* in the context of harm to consumers from animal products in the food supply.[6] *Ctr. for Envtl. Health v. Perdue*, No. 18-CV-01763-RS, 2018 WL 9662437, at *5 (N.D. Cal. Aug. 21, 2018). In *Center for Environmental Health*, the Court distinguished *Clapper* and held that plaintiffs' harms stemming from the U.S. Department of Agriculture's allowance of non-organic animal products to be sold under the organic label, which reduced consumer confidence in the organic label and required consumers to take additional steps to verify that products labeled as "organic" met their personal standards, were not hypothetical. *Id.* These are exactly the harms suffered by Plaintiffs' members here, *e.g.,* Valentine Decl. ¶ 9; Peters Decl. ¶ 13; Kowalski Decl. ¶¶ 10–11, conferring standing.

4. Plaintiffs' Harms Constitute Injury-in-Fact Under NEPA.

With respect to Plaintiffs' NEPA claims, the FDA and Elanco ignore the well-worn standing doctrine for environmental harms laid out in *Summers v. Earth Island Institute*:

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[6] This contextual distinction renders *Herrington v. Johnson & Johnson Consumer Companies, Inc.*, No. C 09-1597 CW, 2010 WL 3448531 (N.D. Cal. Sept. 1, 2010), and the list of product liability class action cases cited by the FDA, Defs. Br. at 14–15, inapposite. In *Herrington*, the court expressly noted that injury based on future risk of harm in environmental cases does not apply to *product liability* actions. *Id.* at *3. Here, Plaintiffs allege present harm that meets the well-established standards for injury *under the FDCA*, and do not rely on the future harm line of environmental cases for their FDCA claim.

increased *threat* of harm is enough to confer standing. *See, e.g.,* 555 U.S. 488, 493 (2009) ("To seek injunctive relief, a plaintiff must show that he is under threat of suffering 'injury in fact. . . .'"); *see also City of Los Angeles v. Lyons*, 461 U.S. 95, 101–02 (1983). It has long been settled that "[o]ne does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough." *Pennsylvania v. West Virginia*, 262 U.S. 553, 593 (1923). In the Ninth Circuit, the fact that "the injury is 'threatened' rather than actual' does not defeat the claim. . . . Nor need the risk of injury be certain, as opposed to contingent." *Idaho Conserv. League v. Mumma*, 956 F.2d 1508, 1515 (9th Cir. 1992). Thus, "an increased risk of future environmental injury constitutes an injury-in-fact for purposes of standing," and Plaintiffs need not prove they are already suffering an environmental harm to have standing. *U.S. Citrus Sci. Council v. U.S. Dep't of Agric.*, No. 117CV00680LJOSAB, 2017 WL 4844376, at *7 (E.D. Cal. Oct. 25, 2017) citing *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 860 (9th Cir. 2005); *see also Ecological Rights Found. v. Pac. Lumber Co.*, 230 F.3d 1141, 1151–52 (9th Cir. 2000); *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 947–48 (9th Cir. 2002). "[T]here is no requirement that the risk of future injury satisfy any particular threshold of significance," *San Luis & Delta–Mendota Water Auth. v. U.S. Dep't of Interior*, 905 F. Supp. 2d 1158, 1171 (E.D. Cal. 2012), nor of certainty, *Nat. Res. Def. Council v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006) (the Circuit "generally require[s] that [a plaintiff] demonstrate a 'substantial probability,'" not certainty, "that they will be injured"). *See also Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 669 (D.C. Cir. 1996) (requiring only "substantial probability that [agency action] created a demonstrable risk, or caused a demonstrable increase in an existing risk, of injury").

Moreover, plaintiffs asserting procedural injury[7] "need not show that the substantive

[7] While failure to follow NEPA's requirements are "procedural" violations, they are not just a harm to a procedure: "Rather, the harm at stake is a harm to the environment, but the harm consists of the added risk to the environment that takes place when governmental decisionmakers make up their minds without having before them an analysis . . . of the likely effects of their decision upon the environment. NEPA's object is to minimize that risk…." *Sierra Club v. Marsh,* 872 F.2d 497, 500 (1st Cir. 1989).

environmental harm is imminent." *Cantrell v. City of Long Beach*, 241 F.3d 674, 679 n.3 (9th Cir. 2001); *see Defs. of Wildlife*, 504 U.S. at 573 n.7 ("The person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy."). To establish standing on a claim asserting procedural injury, Plaintiffs must only show that "(1) the [defendants] violated certain procedural rules; (2) these rules protect [plaintiffs'] concrete interests; and (3) it is reasonably probable that the challenged action will threaten their concrete interests." *Citizens for Better Forestry v. U.S. Dep't of Agric.*, 341 F.3d 961, 969-70 (9th Cir. 2003). In *Citizens for Better Forestry*, plaintiffs brought a NEPA challenge to a nationwide forest management rule that had not yet been applied in developing any forest plans or site-specific projects, and the Ninth Circuit held they had standing to challenge the rule with no obligation to "assert that any specific injury will occur in any specific national forest." *Id.* at 971. The Ninth Circuit explicitly rejected the assertion that the rule was too many steps removed from on-the-ground harm to plaintiffs, noting that the Ninth Circuit has repeatedly rejected this contention and heard challenges to authorizations that constituted the first step in the chain of causation. *Id.* at 973. Accordingly, an environmental plaintiff need not assert that any specific injury will occur in any specific location; rather, "the asserted injury is that environmental consequences might be overlooked as a result of deficiencies in the government's analysis under environmental statutes." *Id*. at 971 (quoting *Salmon River Concerned Citizens v. Robertson,* 32 F.3d 1346, 1355 (9th Cir.1994)).

Plaintiffs satisfy this standard. The FDA's authorization of the use of Experior is the primary, programmatic action from which any later site-specific impacts will flow. Had the FDA adequately considered the effects of Experior on the environment, Plaintiffs' members could be assured that Experior would not negatively impact their enjoyment of the areas where they live and recreate. *See* Lobdell Decl. ¶ 17; Kowalski Decl. ¶ 14; Schutt Decl. ¶ 12. And while NEPA does not guarantee any particular outcome, an adequate analysis would have ensured that the FDA had a meaningful opportunity to order mitigation measures if it found them to be necessary to protect the environment. *See Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 47 (2008) (Ginsburg, J., dissenting) (describing NEPA review as "action-forcing" because it can lead to

"potential mitigation measures and alternatives to the proposed course of action"). As in *Citizens for Better Forestry*, Plaintiffs here have shown they are injured by the FDA's inadequate NEPA analysis without waiting for site-specific effects of Experior's approval. *See* Lobdell Decl.; Kowalski Decl.; Schutt Decl.

C. Plaintiffs' Injuries Are Fairly Traceable to FDA's Action and Redressable by this Court.

Despite the FDA's and Elanco's attempts to introduce speculation into the causal chain of Plaintiffs' harm,[8] Plaintiffs' consumer and environmental injuries are specifically attributable to the FDA's action and not the result of "independent action of some third party not before the court." *Defs. of Wildlife*, 504 U.S. at 560. The FDA alone has the statutory authority to approve animal drugs under the FDCA, as well as the statutory duty to consider the environmental effects of an animal drug approval under NEPA—and it alone has exercised that authority to allow Experior on the market. The FDA's arguments therefore distract from the straightforward inquiries under these prongs of standing and fundamentally miss the point: Plaintiffs challenge *the FDA's faulty approval*, not the later application of the approval in specific contexts.

The FDA and Elanco fail to note that in cases like this involving procedural violations, where "[t]he person who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability," *Defs. of Wildlife*, 504 U.S. at 572 n.7, there is no requirement to "establish that correcting the procedural violation would necessarily alter the final effect" on the plaintiffs' interest, *Mendoza v. Perez*, 754 F.3d 1002, 1010 (D.C. Cir. 2014). The connection between "the procedural step" of complying with NEPA and the "substantive result" is "[a]ll that is necessary for standing." *Envtl. Def. Fund v. Envtl. Prot. Agency*, 922 F.3d 446, 453 (D.C. Cir. 2019) (internal quotation marks omitted). Plaintiffs have thus shown that their injuries are "fairly traceable to the challenged action[s] of the [Federal Defendants], and not the result of the independent action of some third party not before the court." *Mendia v. Garcia*, 768 F.3d 1009, 1012 (9th Cir. 2014) (quoting

[8] Elanco does not contend that Plaintiffs lack redressability or traceability for their FDCA claims, only for their NEPA claims. *See* Elanco's Mot. at 13–16 (arguing injuries not traceable "to FDA's NEPA violations" and redressability "in the NEPA context," specifically).

Bennett v. Spear, 520 U.S. 154, 167 (1997)). The FDCA is the statutory authorization for Experior's use, and it is therefore the direct cause of the alleged injury. *See Sierra Club v. Trump*, 977 F.3d 853, 876 (9th Cir. 2020).

Under NEPA, regardless of what other agencies may later do to counteract the FDA's approval, it is the FDA that bore the burden of adequately considering Experior's environmental impacts—and as the regulatory body solely responsible for Experior's approval, it is the FDA that held the power to mitigate Experior's environmental effects.[9] Experior's efficacy is predicated on it having an environmental effect (i.e., reducing ammonia emissions), and it focuses exclusively on altering emissions from cow manure. It is truly shocking for FDA to now say any consideration of Experior's actual, real-world environmental effects, and specifically Experior's effects on cow manure and manure-laden agricultural runoff, is beyond the scope of the FDA's review under NEPA. In making this argument, the FDA all but concedes that it did not adequately consider the scope of direct, indirect, and cumulative effects of Experior's presence in cow manure and the environment. These are precisely the type of procedural harms that would be redressed by an order requiring the FDA to conduct an adequate NEPA analysis.

Likewise under the FDCA, courts have rejected the same attempts the FDA makes here to place blame on other actors. The possibilities that federal agencies might regulate effectively such that Experior's harms are reduced or that CAFO operators will decide not to use Experior do not change the fundamental fact that Experior is now allowed in the food supply and the environment. The FDA's action "expressly permit[s]" Elanco, as the drug manufacturer, and CAFO operators, as the ultimate users of the product, to market and use Experior, respectively. This is true "regardless of the manufacturer's ultimate decision to do so." *Ctr. for Food Safety v.*

[9] While beside the point, Plaintiffs note that contrary to Elanco's assertions, CAFOs are generally *not* regulated by other laws. *See Nat'l Pork Producers Council v. EPA*, 635 F.3d 738, 751 (5th Cir. 2011) (prohibiting the EPA from "impos[ing] a duty to apply for a [NPDES] permit on a CAFO that 'proposes to discharge' or any CAFO before there is an *actual* discharge" and a likelihood that those actual discharges will continue) (emphasis in original). The EPA does not even know where many CAFOs are located, much less regulate their pollution. 76 Fed. Reg. 65,431 (Oct. 21, 2011).

Price, No. 17-cv-3833, 2018 WL 4356730 at *7 (S.D.N.Y. Sept. 12, 2018). Thus, "a manufacturer's decision to use a potentially unsafe substance in food does not negate the fact that FDA's [action] ultimately allows" them to, which establishes the causation necessary to achieve standing. *Id.* Plaintiffs' allegations are to be taken as true at the pleading stage, and these allegations demonstrate that Plaintiffs "face[] a *present, immediate* risk of exposure" to Experior "as [] consumer[s] of beef products—not a future risk that awaits intervening events." *Baur*, 352 F.3d at 640. Accordingly, even if "a chain of contingencies may need to occur" for Plaintiffs to actually suffer negative health effects as a result of their exposure to Experior residues in beef, "it is not the *materialization* of the feared risk" but the risk itself that must be "certainly impending" to satisfy standing. *Id*.

The FDA and Elanco contend that Plaintiffs' consumer harms are "self-inflicted" to avoid responsibility for them, but it is the opposite: the FDA's action renders Plaintiffs unable to avoid the harm befallen them, despite their efforts. Where consumer plaintiffs lack the necessary information to protect themselves from risk, their harms are not self-inflicted. *See Nat. Res. Def. Council*, 710 F.3d at 82 (finding on summary judgment that plaintiffs had standing "[c]onsidering the potential harms caused by triclosan-containing soap together with FDA's inability to confirm that the soap will not cause these harms, and keeping in mind that the FDCA establishes an interest in being protected from products of unproven safety . . . ."); *see also Nat. Res. Def. Council v. U.S. Consumer Product Safety Comm'n*, No. 16-cv-9401, 2017 WL 3738464 (S.D.N.Y. Aug. 18, 2017) (finding standing based on exposure to phthalates where members of plaintiff organizations could not avoid phthalates in plastics); *Ctr. for Food Safety v. Price*, 2018 WL 4356730 at *7 (finding standing based on inability to avoid potentially unsafe products in the food supply). In *Natural Resources Defense Council v. FDA*, for example, the court held—contrary to the FDA's argument that the member's injury was self-inflicted because she could have used different soap that did not contain the potentially harmful substance at issue—that the plaintiffs satisfied the causation prong of the injury-in-fact analysis because, "but for FDA's challenged inaction, triclosan-containing soaps would not be available on the market." *Id.* at 85. The same is true here. *See, e.g.,* Peters Decl. ¶¶ 6, 12; Bearce Decl. ¶ 7; Kowalski

¶¶ 10–11.

The FDA similarly seems to rely on the fact that feedlots will continue to exist and that other beta-agonists will continue to be used in their attempt to defeat redressability. Far from having to show that the entire CAFO industry would disappear if Experior were not approved, to meet "the minimal burden required at the pleading stage to demonstrate redressability," Plaintiffs need only allege that the FDA action "consistent with the mandates of the FDCA would, among other things, likely reduce members' risk of exposure" to the substance at issue, *Ctr. for Food Safety,* 2018 WL 4356730 at *8, and that their environmental injuries might be relieved if the agency were to fulfill its statutory obligations. *Defs. of Wildlife*, 504 U.S. at 572 n.7; *see also Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) ("When a litigant is vested with a procedural right, the litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant."). Plaintiffs have done so here. Moreover, both the FDCA and NEPA *require* Experior's effects to be considered in combination with other beta-agonists already on the market: the FDCA mandates consideration of "the cumulative effect on man or animal of [a proposed new] drug, taking into account any chemically or pharmacologically related substance," which here includes beta-agonists already on the market, 21 U.S.C. § 360b(d)(2)(B), and NEPA likewise requires consideration of cumulative effects, 40 C.F.R. § 1508.8. The FDA's argument that Plaintiffs cannot consider Experior's cumulative effects when added to other beta-agonists in the food supply and the environment all but admits that it does not understand—and therefore could not have fulfilled—the proper scope of its analysis under the FDCA or NEPA. Unfortunately for the FDA and Elanco, Plaintiffs are legally entitled to adequate analyses that account for the specific harms flowing from Experior's approval, and its cumulative effects with other beta-agonists in the food supply and the environment.

If there still were any question as to the Court's ability to redress Plaintiffs' harms, it is easily addressed by the fact that the FDA and Elanco simply have no authority to put Experior on the market if the Court holds that its current approval is illegal. *See Sierra Club v. Trump*, 977 F.3d at 876 (finding redressability because "[t]he Federal Defendants have no authority to

undertake the border wall projects if the Court holds that Section 2808 does not authorize construction"). If the FDA were ordered by this Court to adequately assess the safety of Experior, consumers would no longer be at risk of exposure to a potentially unsafe drug through residues in the meat they eat, including the cumulative amounts of Experior residues combined with the residues of other beta-agonist drugs in the food supply; at a minimum, it would restore consumers' confidence in the FDA and in the safety of the meat they eat. *See* Valentine Decl. ¶ 11; Bearce Decl. ¶ 17; Peters Decl. ¶ 16; Kowalski Decl. ¶ 14. Similarly, if the Court ordered a proper NEPA analysis, rural residents and outdoor recreationalists would be able to enjoy their homes and local environments free from the uncertainty about Experior's presence and the threat of harm to them, and at the very least would be able to arm themselves with accurate information about Experior's environmental effects. *See* Lobdell Decl. ¶ 17; Kowalski Decl. ¶ 14; Schutt Decl. ¶ 12. This direct line between the Court's decision and Plaintiffs' harms satisfies Article III's requirements.

II. Plaintiffs Exhausted Administrative Remedies.

Plaintiffs exhausted the FDA's administrative remedy by filing the Stay Petition, alerting the Agency to Plaintiffs' concerns with its approval, and providing the Agency the first opportunity to correct its mistakes. This exhausts both the FDA's stated administrative remedy as well as complies with the Ninth Circuit's issue exhaustion requirements. Plaintiffs' claims and their requests for relief are consistent with the Stay Petition. No further exhaustion is required. This Court has jurisdiction to hear Plaintiffs' claims.

A. FDA Regulations Permit Exhaustion Through a Stay Petition.

The FDA regulations provide for review of final agency action, *see* 21 C.F.R. § 10.45, and there can be no doubt that the FDA's response to a stay petition is final agency action. The FDA's regulations make this point abundantly clear:

> The Commissioner's final decision constitutes final agency action (reviewable in the courts under 5 U.S.C. 701 et seq. and, where appropriate, 28 U.S.C. 2201) on a petition submitted under § 10.25(a), on a petition for reconsideration submitted under § 10.33, *on a petition for stay of action submitted under § 10.35*, on an advisory opinion issued under § 10.85, on a matter involving administrative action which is the subject of an opportunity for a hearing under § 16.1(b) of this chapter, or on the issuance of a final regulation published in accordance with § 10.40…

21 C.F.R. § 10.45(d) (emphasis added). Here, Plaintiff ALDF submitted a Stay Petition under section 10.35. FAC ¶ 10. The FDA received the Stay Petition, reviewed it, and issued a denial letter, acknowledging Plaintiffs' concerns. FAC ¶¶ 11, 125–26, 128–30. Under the FDA's regulations, these facts alone are sufficient to find that Plaintiffs exhausted their administrative remedies.

The FDA's regulations provide further support for this Court's jurisdiction. As noted by Elanco, a "request that the Commission take or refrain from taking any form of administrative action must first be the subject of a final administrative decision *based on a petition* submitted under § 10.25(a)…" 21 C.F.R. § 10.45(b) (emphasis added). What Elanco fails to note is telling. Instead of quoting section 10.25(a) in its entirely, it conspicuously points only to section 10.25(a)(2) while ignoring section 10.25(a)(1). When read in full, section 10.25(a) permits many types of FDA petitions to exhaust administrative remedies, such as food additive petitions, new drug applications, or any petition "in [a] form specified in other [FDA] regulations:"

> An administrative proceeding may be initiated in the following three ways: (a) An interested person may petition the Commissioner to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action. A petition must be either: (1) In the form specified in other applicable FDA regulations, e.g., the form for a color additive petition in § 71.1, for a food additive petition in § 171.1, for a new drug application in § 314.50, for a new animal drug application in § 514.1, or (2) in the form for a citizen petition in § 10.30.

Id. at 10.25(a). The FDA itself confirms this point in its Motion to Dismiss: "FDA regulations provide broad opportunities for citizens to petition FDA for different types of relief—including through submitting 'citizen petitions' and '*petitions for stay of action*'—and to comment on petitions that are submitted." Defs.' Mot. 6 (emphasis added). As noted above, 21 C.F.R. section 10.45(d) specifies that a decision on a petition for stay of action submitted under section 10.35 is final agency action "reviewable in the courts." A petition for a stay of action is of a "form specified in … [FDA] regulations" and exhausts administrative remedies for the issues and claims raised therein.

The window for filing a petition for a stay of administrative action is narrow; it must be filed within 30 days of the particular approval pending further review. *Id.* § 10.35(b). This short

timeframe requires interested parties to act fast in order to raise concerns with the Agency to limit the potential of harm to the applicant, the public, and the environment. ALDF thus timely filed a Stay Petition to halt Experior's approval in order that the Agency be provided an immediate opportunity to address Plaintiffs' concerns. *Ctr. for Food Safety v. Hamburg*, 142 F. Supp. 3d 898, 902 (N.D. Cal. 2015) ("The purpose of the exhaustion doctrine is to allow the administrative agency in question to exercise its expertise over the subject matter and to permit the agency an opportunity to correct any mistakes that may have occurred during the proceeding, thus avoiding unnecessary or premature judicial intervention into the administrative process."). The Stay Petition accomplished the precise goals laid out by *Center for Food Safety.* Elanco's reliance on *Center for Food Safety* to argue the contrary is misplaced.

In *Center for Food Safety*, plaintiffs challenged several animal drug approvals that were many years, and in some cases decades, old. There, the district court offered to stay the case so that plaintiffs could file a citizen petition to provide the FDA the opportunity to apply its expertise; due to the age of the approvals at issue, a stay petition was not an option under FDA's regulations. *Ctr. for Food Safety*, 142 F. Supp. 3d at 901. The only petition available to the *Center for Food Safety* plaintiffs was a "citizen petition." In an unpublished memorandum disposition, the Ninth Circuit stated that, under those facts, the district court's offer to stay plaintiffs' case to allow plaintiffs time to exhaust with a citizen petition was appropriate. *Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302 (9th Cir. 2016). While Elanco relies on this memorandum disposition in support of its exhaustion argument, the Ninth Circuit did not create an expansive rule that the only way to exhaust administrative remedies under FDA's regulations is to file a citizen petition, as Elanco suggests. Instead, the limited order applied only to "the facts of [that] case." *Id.*

Elanco's similarly stretched summary of *Association of American Physicians & Surgeons, Inc. v. FDA,* 539 F. Supp. 2d. 4 (D.D.C. 2008) does not support Elanco's fabricated citizen petition requirement. There, the district court found that plaintiffs failed to exhaust because "the agency was never provided with an opportunity to address plaintiffs' requests that the FDA take certain actions, such as amending the label of [the challenged drug]." 539 F. Supp.

2d. at 21. The district court suggested that there was a process that plaintiffs could engage in—the citizen petition process—but it did not grapple with whether there were other processes by which an interested party could provide the agency with the opportunity to address its concerns. *Id.* at 22. Finally, the court noted that an interested party that files a petition and receives a final decision does not need to exhaust further. *Compare id. with* Elanco's Mot. 20 (suggesting that already exhausted claims must be further exhausted). A party needs only one "final agency decision on *its* challenge to the approval of a [NADA], but consistent with § 10.45(e) would not then have to seek 'reconsideration or … a stay' before requesting judicial review." 539 F. Supp. 2d. at 22. Here, the Agency was "provided with an opportunity to address [P]laintiffs' requests that the FDA take certain actions" such as comply with the FDCA and NEPA. *See id*. at 21. The FDA issued a final decision on the Stay Petition, which exhausted administrative remedies.

B. The Stay Petition Alerted the Expert Agency to Plaintiffs' Concerns and Provided the Agency the First Opportunity to Correct its Mistakes.

Plaintiffs exhausted administrative remedies by filing a Stay Petition with the FDA, to alert the Agency of Plaintiffs' concerns with Experior's approval and provide the Agency the first opportunity to correct its mistakes. This satisfied the FDA's regulatory exhaustion requirements, as explained above. Plaintiffs have also satisfied the Ninth Circuit's familiar "issue exhaustion" requirements, that a plaintiff is required provide "sufficient notice to the agency" to afford it the opportunity to rectify the violations that the plaintiffs alleged.'" *See Nat'l Park Conservation Ass'n v. BLM*, 606 F. 3d 1058, 1065 (9th Cir. 2010) (quoting *Native Ecosystems v. Dombeck*, 304 F.3d 886, 899 (9th Cir. 2002)).

While there is no "bright-line standard" for meeting the issue exhaustion requirement, the Ninth Circuit interprets it broadly. *Id*. The Ninth Circuit's decision in *Lands Council v. McNair*, 629 F.3d 1070 (9th Cir. 2010), underscores this expansive approach, clarifying that a plaintiff need only alert the action agency "in general terms" to a particular issue as long as the agency is given the opportunity to "bring its expertise to bear to solve [the] claim." 629 F.3d at 1076 (quoting *Native Ecosystems Council*, 304 F.3d at 900). Plaintiffs need not state their claims in precise legal terms and need only raise an issue "with sufficient clarity to allow the decision

maker to understand and rule on the issue raised." *Id.* (quoting *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 968 (9th Cir. 2006)). It is not even necessary to cite the relevant statute or regulation to exhaust a legal issue or invoke the exact legal terms of art drawn from those statutory authorities. *Idaho Sporting Cong., Inc. v. Rittenhouse*, 305 F.3d 957, 965–66 (9th Cir. 2002); *cf. Native Ecosystems Council*, 304 F.3d at 900. Instead, a plaintiff can exhaust an issue by articulating the particular reason why an agency's action is improper. *See, e.g., Nat'l Parks & Conservation Ass'n*, 606 F.3d at 1066. This achieves the purpose of exhaustion: to "prevent premature interference with agency processes so that the agency may function efficiently and so that it may have an opportunity to correct its own errors, to afford the parties and the courts the benefit of its review." *Tamosaitis v. URS Inc.*, 781 F.3d 468, 478 (9th Cir. 2015), *as amended* (citation omitted).

The Stay Petition did precisely what the Ninth Circuit requires: it alerted the FDA of Plaintiffs' concerns and gave the Agency the opportunity to correct its errors prior to judicial review. Plaintiffs' concerns—the same concerns that are the subject of this litigation[10]—were well-reasoned and supported. ALDF retained an expert to "review and assess the adequacy of Experior's approval and associated NEPA documents." Walden Decl. ¶ 15. ALDF's expert

[10] To be sure, Plaintiffs' concerns in the Stay Petition mirror those in the First Amended Complaint. *Compare* Stay Petition at 2 (December 6, 2018), *available at* https://beta.regulations.gov/docket/FDA-2018-P-4656/document (last visited November 29, 2020) ("FDA violated the [FDCA] by approving a drug that has not been shown to be safe and effective in target animals"), *with* FAC ¶ 2 ("Experior has not been shown to be safe and effective . . . ."); *compare* Stay Petition at 2–4 ("FDA violated the [FDCA] by failing to consider the public health effects of the drug approval."), *with* FAC ¶ 8 ("In approving this drug FDA also failed to consider the increased food safety and public health risk of its decision."); *compare* Stay Petition at 4–6 ("FDA violated NEPA by failing to consider the cumulative effects of the drug approval."), *with* FAC ¶¶ 130–31 ("FDA did not consider the cumulative environmental effects of the use of the drug over time or in combination with other drugs, and especially other beta-agonists that are already present in the environment."); *compare* Stay Petition at 6 ("FDA violated NEPA by failing to consider the effects on health and well-being of target animals."), *with* FAC ¶ 137 ("FDA dismissed these findings [related to animal health concerns] as non-significant."); *compare* Stay Petition at 7–8 ("FDA violated NEPA by finding no significant impact despite known and unknown environmental effects."), *with* FAC ¶ 130 ("FDA did not—either originally or in response to ALDF's Petition—adequately consider the effects that the presence of Experior in cow feces will have on the environment."); *compare* Stay Petition at 8 ("FDA violated NEPA by finding no significant impact despite known and unknown environmental effects"), *with* FAC ¶¶ 149–158 (same).

"identified critically significant deficiencies in FDA's approval decision," which prompted ALDF to immediately bring those concerns to the Agency. *Id.* The Petition sought review of Experior's safety and effectiveness in target animals and humans and its effect on the environment. *Id.* The Stay Petition addressed Plaintiffs' concerns regarding "beta-agonist effects on animals, consumers, and the environment and the lack of information about Experior's comparative effects." *Id*. Elanco's suggestion that Plaintiffs' well-reasoned concerns must be presented a second time to the Agency with more detail is contrary to the Ninth Circuit's expansive approach on exhaustion, requiring only that a plaintiff alert the action agency "in general terms" to a particular issue. *Lands Council*, 629 F.3d at 1076.

The FDA's response confirms that Plaintiffs placed it on notice of the very issues they raise here. *Or. Nat. Desert Ass'n v. McDaniel*, 751 F.Supp. 2d 1151, 1161 (D. Or. 2011) ("[W]hile language in an agency decision actually addressing the plaintiff's issue confirms that the plaintiff placed the agency on notice of that issue, such agency responsiveness is apparently not required for issue exhaustion.") (*comparing Native Ecosystems Council*, 304 F.3d at 899 (finding that the agency addressed the issue), *with Nat'l Parks & Conservation Ass'n*, 606 F.3d at 1066 (holding that an issue had been exhausted even though the agency did not address it). The FDA responded to each of Plaintiffs' concerns, and while Plaintiffs challenge the adequacy and accuracy of the response, the FDA's response is a plain indication of Plaintiffs' exhaustion. Elanco's contention that the Agency did not have the first opportunity to address Plaintiffs' concerns is simply unfounded.

Finally, Plaintiffs' issue exhaustion nullifies any suggestion that all Plaintiffs must separately exhaust administrative remedies by individually raising the same concerns with the agency. The FDA had "independent knowledge of the very issue that concerns Plaintiffs in this case," and there is no requirement that each individual Plaintiff separately point out each concern with the FDA in order to preserve its ability to challenge a proposed action. *See 'Illio'ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1092 (9th Cir. 2006) (citing *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 765 (2004)). The FDA was afforded an opportunity to apply its expertise to assess Plaintiffs' claims in the first instance prior to judicial intervention, exhausting administrative

remedies.

C. A Stay of this Action Requiring Plaintiffs to File a Duplicative Petition Would Waste Judicial and Administrative Resources and Cause Unnecessary and Unwarranted Delays.

The purpose of the APA is to remove obstacles to judicial review of agency action, not to create them. *Bowen v. Massachusetts*, 487 U.S. 879, 904 (1988) (citing *Shaughnessy* v. *Pedreiro*, 349 U.S. 48, 51 (1955)); *see also Darby* v. *Cisneros*, 509 U.S. 137,146–47 (1993) (citations omitted). Elanco ignores this, and instead manipulates the FDA's regulations to create additional hurdles for interested parties to raise concerns with FDA actions. Elanco suggests that Plaintiffs should file a Stay Petition, and if that Petition is denied, file another separate petition raising the exact same substantive concerns with the Agency before they can challenge a decision—a decision that is already final agency action in and of itself—in court.[11] Yet the APA's judicial review provisions cover a "broad spectrum of administrative actions," including the Stay Petition, and the APA's "'generous review provisions' must be given a 'hospitable' interpretation" here. *Bowen*, 487 U.S. at 904 (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 140–41 (1967) (footnote omitted)).

Plaintiffs cannot be required to exhaust administrative remedies by filing a second, separate petition requesting that the FDA undertake the environmental analysis that it was legally required to conduct for each new animal drug approval. This is especially true considering it is the FDA, not Plaintiffs, that has a statutory duty to comply with NEPA and the FDCA. *Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 764–65 (2004). The FDA is required to comply with NEPA in approving animal drugs. 21 C.F.R. § 25.1. Compliance with NEPA is not within the FDA's discretion—it is mandatory for all federal agencies, *see Friends of the Clearwater v.*

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[11] There is no doubt that animal drug approvals constitute reviewable final agency actions. Elanco submitted petitions under 21 C.F.R. § 10.25(a), and the FDA made final administrative decisions on those petitions. *Stauber,* 895 F. Supp. at 1188 ("[T]he secretary's decisions on new drug applications constitute final agency action for purposes of exhaustion.") (citing 21 C.F.R. §§ 10.25, 10.45). Nevertheless, Plaintiffs exhausted their own administrative remedies by filing a stay petition with the FDA, to alert the agency of Plaintiffs' concerns and provide the "expert agency an opportunity to correct any mistakes." Elanco's Mot. 21 (citing *Buckingham v. Dep't of Agric.*, 603 F.3d 1073, 1080 (9th Cir. 2010)).

Dombeck, 222 F.3d 552, 558–59 (9th Cir. 2000), and specifically required by the FDA's own regulations, 21 C.F.R. pt. 25. The FDA's NEPA regulations instruct the Agency to assess environmental factors "at the earliest possible time to ensure that planning and decisions reflect the environmental values, to avoid delays later in the process, and to avoid potential conflicts." *Id.* § 25.10(b). "[F]ulfillment of this vital responsibility should not depend on the vigilance and limited resources of environmental plaintiffs" in pointing out the FDA's flaws *multiple times*. *City of Davis v. Coleman*, 521 F.2d 661, 670–71 (9th Cir. 1975).

Where, as here, Plaintiffs lacked any opportunity to participate in or challenge the Agency's action during the review period, *see* 21 C.F.R. § 10.40(e)(3); *Ecology Ctr. of La., Inc. v. Coleman*, 515 F.2d 860, 865 (5th Cir. 1975); *Lands Council v. Vaught*, 198 F. Supp. 2d 1211, 1240–41 (E.D. Wash. 2002) (citing *Nw. Tissue Ctr. v. Shalala*, 1 F.3d 522, 530 (7th Cir. 1993)), it can only be expected to raise its concerns at the first available opportunity. Plaintiff ALDF did just that. That Plaintiffs' litigation remedies ask for slightly more nuanced relief than ALDF's Stay Petition did does not undo Plaintiffs' exhaustion. Plaintiffs seek the nearly identical relief here that was presented in the Stay Petition: an order enjoining, vacating, or setting aside the FDA's approval unless—and until—it complies with the FDCA, NEPA, the APA, and the FDA's own regulations. Even so, the "relief requested" is not determinative of whether the Agency had advanced notice of and opportunity to correct its mistakes. Here, the FDA had advanced notice of Plaintiffs' claims and it failed to correct its mistakes.

III. Plaintiffs' First Claim for Relief States a Claim.

Plaintiffs' First Claim for Relief—that the FDA unlawfully denied ALDF's Stay Petition—clearly and concisely set forth Plaintiffs' legal theory, explaining why Plaintiffs are entitled to relief. It also provides the Court with a "connected remedial request," *see* Elanco's Mot. 23 (arguing without citation to authority that a claim requires a "connected remedial request"), because the Complaint itself, incorporated by reference in the first claim, fairly stated the nature of relief that Plaintiffs are entitled to receive. Familiar pleading principles teach that the request for relief is not a part of a cause of action; the cause of action is a function of the facts and allegations of the Complaint. Plaintiffs have stated a cause of action and requested

appropriate relief.

Federal Rule of Civil Procedure 8 requires only a "short and plain statement of the claim showing that the pleader is entitled to relief," in order to give the "[d]efendant notice of what the … claim is and the grounds upon which it rests. . . ." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* at 570. A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* at 556. "Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *See Ashcroft v. Iqbal,* 556 U.S. 662, 679 (2009). Nevertheless, all ambiguities or doubts must also be resolved in the plaintiff's favor. *See Jenkins v. McKeithen*, 395 U.S. 411, 421 (1969).

Plaintiffs' first claim plainly meets this standard. It methodically lays out the regulations that allow an interested person to submit an administrative request to stay an action, 21 C.F.R. § 10.35; the factors the FDA must consider when deciding whether to grant a stay, *id*. § 10.35(e)(1); the exhaustion requirements for such a petition, *id*. § 10.45(c); how the Stay Petition met the factors for a stay; and that the FDA erroneously denied the Stay Petition under its regulations. FAC 35–36. It further cites section 706(2) of the APA because the FDA "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Assoc. v. State Farm Mutual Auto. Ins. Co*., 463 U.S. 29, 43 (1983); FAC 36. Finally, the first claim states generally that the FDA violated the APA in denying the Stay Petition. FAC 36. Taken together, this puts the parties and the Court on notice of what Plaintiffs' first claim is and the grounds upon which it rests.

Plaintiffs also comply with FRCP 8(a)(3) by including a prayer for relief in the Complaint. Plaintiffs request that the Court enjoin or vacate the FDA's approval of Experior

unless and until such time as the FDA complies with the APA, the FDCA, and NEPA. ALDF's Stay Petition requested nearly identical relief: "a stay of indefinite duration, unless and until such time as FDA complies with the requirements of the [APA], [FDCA], [NEPA], and [ESA]." FAC ¶ 126; *id.* at 28 n.15 (citing Stay Petition); Stay Petition 1. Nevertheless, Elanco makes the tortured argument that Plaintiffs' First Claim for Relief "fails to state a claim" because the separate request for relief does not use the word "stay." That Plaintiffs did not use the word "stay," and instead used the more appropriate term "enjoin," in the request for relief, is a distinction without a difference.

The prayer for relief is a wholly separate section of the Complaint and one that does not itself form any part of Plaintiffs' actual claims under FRCP 8(a)(2). *Foust v. Page*, No. CV-12-08115, 2014 WL 3340916 *3 (D. Az. July 8, 2014) (finding that a prayer for relief is required by FRCP 8(a)(3), but it does not itself form any part of a plaintiff's actual claims under Rule 8(a)(2)); *see also Greene v. Bowen*, 639 F. Supp. 554, 562 (C.D. Cal. 1986), *remanded on other grounds*, 844 F.2d 791 (9th Cir. 1988) ("[A]s an ordinary matter, the plaintiff's prayer is not considered part of the complaint."); *Laird v. Integrated Res., Inc.*, 897 F.2d 826, 841–42 n.69 (5th Cir. 1990); *Bontkowski v. Smith*, 305 F.3d 757, 762 (7th Cir. 2002). Indeed, courts have consistently held that a prayer for relief is a remedy, not a claim, and thus a Rule 12(b)(6) motion to dismiss for failure to state a claim is not a proper vehicle to challenge any alleged deficiencies in a prayer for relief. *See, e.g., Monaco v. Liberty Life Assurance Co.*, No. C06-07021 MJJ, 2007 WL 420139, at *6 (N.D. Cal. Feb. 6, 2007) ("[A] complaint is not subject to a motion to dismiss for failure to state a *claim* under Rule 12(b)(6) because the prayer seeks relief that is not recoverable as matter of law.") (emphasis in original); *Jordan v. United States*, No. 15-cv-1199 BEN (NLS), 2015 WL 5919945, at *2–3 (S.D. Cal. Oct. 8, 2015) ("A prayer for damages constitutes a remedy, not a claim within in the meaning of Rules 8(a)(2) or 12(b)(6). Thus [a] prayer for relief does not provide any basis for dismissal under Rule 12.") (internal quotation and citation omitted).

Federal Rule of Civil Procedure 54 underscores the impropriety of dismissing claims based on the alleged adequacies of the request for relief. Rule 54(c) states that "final judgment

should grant the relief to which each party is entitled, even if that party has not demanded that relief in its pleadings." Fed. R. Civ. P. 54(c). It thus makes little sense to dismiss a properly pled claim for relief based solely on what is allegedly missing from the prayer. Plaintiffs are entitled to whatever relief is appropriate to the claims alleged in the Complaint, if proved. *Id*; *see also Z Channel, Ltd. v. Home Box Office, Inc.,* 931 F.2d 1338, 1341 (9th Cir. 1991) (reversing summary judgment and holding that a plaintiff may be entitled to damages even though the complaint seeks only injunctive and declaratory relief). Plaintiffs can be entitled to relief even when they fail to include a prayer for relief as long as the complaint otherwise fairly states the nature of relief, and plaintiffs proved the right to relief. *See, e.g., Int'l Harvester Credit Corp. v. East Coast Truck,* 547 F.2d 888, 891 (5th Cir. 1977). Thus, the "relief provided for [each of Plaintiffs'] various claims will be determined if any entitlement to relief is proved." *Delano Farms Co. v. Cal. Table Grape Comm'n*, 623 F. Supp. 2d 1144, 1183 (E.D. Cal. 2009).

The section of the APA governing preliminary relief, 5 U.S.C. § 705, allows "the reviewing court" to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings" to "the extent necessary to prevent irreparable injury." 5 U.S.C. § 705. It therefore "authorizes courts to *stay agency* [*action*] pending judicial review." *See Mexichem Specialty Resins, Inc. v. Envtl. Prot. Agency*, 787 F.3d 544, 562 (D.C. Cir. 2015) (Kavanaugh, J., dissenting in part). Plaintiffs requested both declaratory and injunctive relief, and all other relief this Court deems is "proper, just, and equitable." FAC 38.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that this Court deny FDA's and Elanco's Motions.

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Respectfully submitted,

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